REMARKS

Claims 18-37 remain pending in the application. Claim 37 has been amended to remove a duplication of a limitation in its part a), replacing the second recitation of a concentration of starch with a limitation appearing in claim 1 of the parent application and relating to a disintegrant component. No new matter is being added.

The claims have been asserted as lacking unity of invention, the claim groupings for inventions not considered to be linked to form a single general inventive concept being as follows:

I. Claim 37, directed to a pharmaceutical composition having a tablet layer comprising Form X of fexofenadine hydrochloride and specific excipients, and a tablet layer comprising a salt of pseudoephedrine and specific excipients.

II. Claims 27-36, directed to a pharmaceutical composition comprising a tablet layer comprising an antihistamine drug and specific excipients, and a tablet layer comprising a decongestant drug and specific excipients.

III. Claims 18-26, directed to a pharmaceutical composition comprising a tablet layer comprising an antihistamine drug and specific excipients, and a tablet layer comprising a decongestant drug and specific excipients.

This determination does not appear to be properly based, and is respectfully traversed in the discussion below.

A requirement for election of an invention to be examined was justified, based *inter alia* on a perceived lack of novelty over U.S. Patent No. 4,996,061 ("Webb et al.") of "at least one Markush alternative." However, applicants' claims do not use any traditional *In re Markush* grouping language, so applicants are not able to determine how this subject relates to their claims. Applicants are claiming alternatives for certain excipient classes, but not in the *Markush* format.

Even if the applicants' claim language could somehow be considered as equivalent to *Markush* claims, there does not appear to be any lack of novelty over Webb et al. Webb et al. disclose multiple-compression tablets having: a discrete zone made with "Formulation (A)" that contains a carrier and a decongestant amount of a sympathomimetic drug; and a discrete zone made with "Formulation (B)" that contains

an antihistaminic amount of a piperidinoalkanol (e.g., fexofenadine) or a salt thereof, and excipients. Focusing on the Webb et al. teachings regarding Formulation (B), there is no teaching in Webb et al. of all of the limitations of the portions of applicants' independent claims relating to tablet layers that contain an antihistamine drug:

> 18. … a) a tablet layer comprising an antihistaminic drug, a cellulose derivative, a polyol, a starch derivative, and a disintegrant …
>
> 27. … a) a tablet layer comprising an antihistaminic drug, cellulose, mannitol, starch, and croscarmellose sodium …
>
> 37. … a) a tablet layer comprising crystalline form X of fexofenadine hydrochloride, about 20 to about 45 percent by weight cellulose, about 10 to about 30 percent by weight mannitol, about 5 to about 25 percent by weight starch, and about 4 to about 15 percent by weight of a disintegrant …

Since the Webb et al. patent does not contain teachings that provide each and every limitation of the applicants' claims, there is no lack of novelty and the justification for imposing an election requirement fails. The requirement therefore is improper and should be withdrawn.

The Office Action also justifies the requirement by asserting that "all these inventions listed in this action are independent or distinct … and there would be a serious search and examination burden …" However, this type of justification pertains only to restriction in applications filed under 35 U.S.C. § 111(a) and is not applicable to the present application that was submitted under 35 U.S.C. § 371. M.P.E.P. 1893.03(d) provides that restriction practice under 37 C.F.R. §§ 1.141-1.146 cannot be used for national stage filings of PCT applications. If the PCT unity of invention requirement is met, the claims should be examined in their entirety.

There clearly is a single inventive concept in the applicants' pending claims, as the more general independent claim 18 encompasses both of the remaining independent claims 27 and 37. Each of these claims is novel over the teachings of Webb et al. Therefore, applicants have improperly been required to elect an invention for prosecution and the requirement should not be maintained.

However, if the requirement is to be maintained, applicants provisionally elect the claims of Group III, including claims 18-26, for an initial examination.

The Office Action further states a requirement for "election of a single disclosed species of histamine and decongestant pair other than fexofenadine form X and pseudoephedrine salt and carrier other than combination of separate layers of cellulose, mannitol, starch croscarmellose sodium. polyvinyl acetate and povidone …" No justification for this requirement was provided, and there is no information regarding why applicants should be prevented from electing any of the recited species. Does this indicate that claims depending from claim 18 would not be examined?

Since the applicants do not understand the species election requirement, their election for commencement of the examination process includes crystalline Form X of fexofenadine hydrochloride (from claim 19), powdered cellulose (from claim 20), mannitol (from claim 21), corn starch (from claim 22), croscarmellose sodium (from claim 23), pseudoephedrine (from claim 24), and a mixture of polyvinyl acetate and povidone (from claim 25).

Withdrawal of the requirements of the Office Action and examination of all pending claims are requested. If any matters remain to be addressed in connection with this response, please contact the undersigned by telephone or facsimile for a prompt resolution.

Respectfully submitted,

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